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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/598,324 06/20/00 OSHLACK

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EXAMINER

HM12/0718

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HAGHIGHATIAN, M

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/598,324

Applicant(s)

OSHLACK ET AL.

Examiner

Mina Haghghatian

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 are vague and indefinite due to "except for microcrystalline cellulose". What does this mean? Claim 10 is also vague because of the word "an" in section (B). This is probably a typing error.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 10-12, 15 and 17 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 12, 19 and

24 of U.S. Patent No. 5,411,745. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to an oral dosage form of powder-layered beads containing pharmaceutical active agent, inert beads and the method of making and method of using the same composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Babu et al (5,073,380) in view of James et al (4,865,851).

Babu teaches oral sustained release pharmaceutical formulation and process, where the tablet or tablet layer is formed by making a wet granulation, using povidone (PVP) in water or alcohol-water as the granulating fluid which is mixed with a pharmaceutical active, microcrystalline cellulose, than drying and milling the granulation and blending with dry powdered smoothness enhancer, e.g. povidone, erosion

promoter, e.g. pregelatinized starch, and compressing the resultant granulation into a tablet with a smooth outer surface, which tablet provides, upon administration, a slow release of the pharmaceutical active (col. 1, lines 49-67; col2, lines 1-19).

Badu teaches that the sustained release matrix can be used alone as a shaped and compressed tablet, or as part of a multi-layered tablet containing an immediate or quick-release layer and a sustained release layer. The preferred process which is utilized to form the most preferred sustained release matrix is to mix together the dry powdered active drug, the dry powdered matrix binding agent, hydroxyethyl cellulose, and the dry powdered wicking agent, microcrystalline cellulose in a mixer/granulator. A granulating fluid or solution is formed by dissolving povidone into water at a ratio of 19.1 grams of povidone to 100 grams of water (col. 4, lines 11-68; col. 5, lines 1-26).

Badu lacks specific teachings on maltodextrin and particle diameter.

James teaches pharmaceutical composition comprising cefuroxime axetil, coated with an integral coating of a lipid or mixture of lipids for oral administration (abstract).

James discloses that a particularly preferred agent with coating properties is maltodextrin (col. 3, lines 42-55). The other agents suitable for the composition are listed as, pregelatinized maize starch, polyvinylpyrrolidone, lactose, talc etc (col. 5, lines 30-56). Also disclosed are the suitable diameters which are below 1000 microns, and particularly below 800 microns (col.6, lines 30-33).

It would have been obvious to a person of ordinary skill at the time the invention was made to have modified the composition of Babu of oral sustained release pharmaceutical formulation by adding the composition of James, because a sustained

release formulation with added benefits of suitable coating agent and the appropriate particle diameter would lead to successfully producing an multi layered formulation, which allows for various rates of dissolution of the active agent.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on MON-FRI from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
Patent Examiner
July 13, 2001


DIANA DUDASH
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